No. 23-55645

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, ex rel. 3729, LLC,

Plaintiff-Relator-Appellant,

v.

EVERNORTH HEALTH, INC., and EXPRESS SCRIPTS, INC.

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of California
Case No. 3:19-cv-01199-TWR-WVG
The Honorable Todd W. Robinson, District Court Judge

PLAINTIFF-RELATOR-APPELLANT'S OPENING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Under Federal Rule of Appellate Procedure 26.1, Plaintiff-Relator-Appellant, 3729, LLC states that no entity owns 10 percent or more of 3729, LLC's stock.

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INTRODUCTION

This appeal addresses the district court's premature dismissal of a quintessential False Claims Act ("FCA") complaint under the FCA's "public disclosure" bar. The so-called public disclosures neither revealed, nor gave rise to a reasonable inference of, a fraudulent scheme. Moreover, the Relators' trove of material additions to these disclosures made Relator an original source that is exempt from the public disclosure bar.

The FCA was designed for complaints just like this one. The taxpayers of this country—via the Department of Defense ("DoD")—bestowed a well-deserved prescription drug benefit on military personnel and veterans. DoD entrusted Express Scripts, Inc. ("ESI"), one of the biggest companies in the country, to fill all mail-order prescriptions under DoD's enormous Tricare program. ESI exploited this trust for its own profit pursuant to a massive, unlawful profit scheme, as detailed in Relator's complaint.

Specifically, ESI illegally over-dispensed prescription refills and over-charged DoD on a systematic, nation-wide basis (indeed, world-wide), providing *265 days per year of extra, unneeded medication—an extra 73%—for every prescription in ESI's enormous auto-refill program*. For no conceivable reason other than greed, ESI set its auto-refill program to refill prescriptions *every 60 days on 90-day prescriptions* (or 20 days on 30-day prescriptions), not just for the first refill but

for *every subsequent refill*, such that the "buffer" of excess medication grew larger with each increasingly premature refill. Through this unlawful program, ESI charged DoD billions-of-dollars in excess dispensing fees and unnecessary drug resupplies, and in the process deprived military personnel and veterans of funds desperately needed for other services.

As outrageous as this may sound, it is not hyperbole. In fact, ESI intentionally targeted the Tricare program for its outrageous conduct. When ESI acted as a pharmacy benefit manager for *other* large groups of insureds (*e.g.*, when ESI was dealing with private insurers, not the government), it did *not* permit its own mail-order pharmacy, or any other pharmacy, to make continuous 60-day renewals on 90-day prescriptions as it did under the Tricare program. ESI knew that this practice systematically and improperly results in an ever-increasing, costly over-supply of medication. But ESI spotted a way to bill DoD for this inexcusable waste and exploited it.

No public source disclosed ESI's fraudulent scheme before the complaint was filed. Nevertheless, the district court invoked the FCA's public disclosure rule based on two sources that had previously reported on general, non-deliberate waste in ESI's mail-order program. Those sources did not come close to disclosing fraud, let alone the method or extent of ESI's scheme.

The first source, a short 2013 article in a military publication, the *Army Times*, reported on poor customer experiences with ESI's mail-order services, including a single instance of a Tricare recipient receiving too much medication from ESI's auto-refill program on 60-day increments rather than 90-day increments. According to the article, this resulted in a "pile" of medication in the veteran's closet and his frustration in not being able to stop the supply of refills through ESI's automated customer service line. The second source—brief public comments in a 2014 Federal Register final rulemaking—contained only vague suggestions from an anonymous "professional association" about possible "unnecessary" waste in the program. Neither of these sources disclosed the actual, system-wide scheme alleged in the complaint, the specific fraudulent intent behind it, ESI's development and implementation of a software algorithm to effectuate it, or ESI's cover-up, which defrauded the government of billions through wrongful calibration of ESI's auto-refill system.

Even if there was a public disclosure, Relator, a limited liability company comprised of individuals with independent, direct knowledge of ESI's fraud—including the former pharmacist-in-charge of ESI's mail-order pharmacy at the center of the scheme—easily satisfies the FCA's "original source" exception to the public disclosure rule. The district court held otherwise, finding that Relator's complaint, *the first to allege, in meticulous detail, an intentional scheme to defraud*

the government, and on a massive scale, somehow made no "material additions" to the previous, limited disclosures. This ruling improperly conflated original source and public disclosure into a single, redundant standard, and effectively made it impossible for Relator to qualify as an original source. Once the district court deemed Relator's allegations to be publicly disclosed, the district court could conceive of no additional information that would be material. But Relator qualifies because it provided detailed, direct evidence of a fraud, including specific evidence of ESI's fraudulent intent, that even the district court deemed, at most, to have been "inferrable" from the information in the public sources. When a public disclosure creates at most a weak inference of fraud, adding critical, direct evidence of fraud, including a cover up and specific intent, is more than sufficient to satisfy the original source exception.

For either or both of these reasons, the district court's dismissal of Relator's complaint should be reversed.

JURISDICTIONAL STATEMENT

The district court had jurisdiction of this matter under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). This Court has jurisdiction under 28 U.S.C. § 1291. Relator timely filed this appeal on July 17, 2023, 3-ER-389-93, from the district court's June 16, 2023 order, 1-ER-002-33, administrative closure of the case on July 12, 2023, 3-

ER-394, and entry of judgment on September 21, 2023, 1-ER-002-34. There are no proceedings remaining below and no related proceedings.

As Relator noted in an addendum to its Notice of Appeal, there was initially a question as to the finality of the June 16 Order. That question has been resolved by the district court's September 21, 2023 order dismissing with prejudice all causes of action asserted by Relator in its complaint, and entry of judgment. *See* 1-ER-035-36, 1-ER-034. In its June 16 order dismissing the complaint, the district court "dismiss[ed] without prejudice" Relator's complaint, and granted Relator 21 days to file an amended complaint. 1-ER-033. The June 16 Order also stated that "*[s]hould Relator decline timely to file an amended complaint, this action will be dismissed* ***without prejudice*** *and this case will be closed without further Order of the court.*" 1-ER-033 (emphasis added). On July 12, 2023, the case was administratively closed by the clerk of the district court after Relator elected not to file an amended complaint. 3-ER-394.

On July 14, 2023, Relator filed its Unopposed Request for Final, Appealable Order, 2-ER-038-41, requesting that the district court enter an order dismissing Relator's action "with prejudice," rather than "without prejudice," to confirm finality for appeal. The Request was not ruled on as of the filing of the Notice of Appeal, but was subsequently granted by the district court on September 21, 2023, with judgment entered that same date. *See* 1-ER-035-36, 1-ER-034. The district court's

September 21 final order and judgment eliminates any question of finality and "cures" any premature filing defect in this appeal. *See Weston Family P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 618 (9th Cir. 2022) (finding that a district court's final order, issued after the filing of a notice of appeal, vested the Ninth Circuit with appellate jurisdiction).

ISSUES PRESENTED

Can disclosures which fail to report or even suggest fraud or fraudulent intent, and fail to report the means by which the fraud was carried out and concealed, invoke the FCA's public disclosure bar?

If such disclosures do invoke the bar, does Relator qualify as an original source by materially adding detailed, direct evidence of a deliberate fraudulent scheme the existence of which was, at most, only implied in the prior sources?

An addendum with the pertinent statutes and regulations referenced herein is bound with this brief at pages A-001-17.

STATEMENT OF THE CASE

A. Relator's Complaint Alleges Massive, Intentional Fraud by ESI on the Tricare Program

ESI is the largest pharmacy benefit manager ("PBM") in the United States, providing pharmacy services to over 85 million people nationwide. 3-ER-342, ¶ 8. In or around 2003, DoD, through its Tricare Management Authority and later its Defense Health Agency ("DHA"), first contracted with ESI to provide retail, mail-

order, and specialty pharmacy services to Tricare beneficiaries. *See* 3-ER-346-47, ¶¶ 23-24. Through Tricare, the United States provides health insurance benefits, including prescription drug coverage, to approximately 9.4 million eligible beneficiaries around the world, including active-duty service members, retirees, and their family members and dependents. 3-ER-346, ¶ 22.

Pursuant to its contractual obligations, DoD purchased medications supplied to—and dispensed by—ESI, which received approximately $17 per dispensing event. 3-ER-346-47, ¶¶ 23-24. The scale of ESI's dispensing under the Tricare program has been massive, totaling 119,400,000 prescriptions in 2017 alone. 3-ER-346-47, ¶¶ 23-24.

1. ESI was expressly forbidden by law and contract from over-dispensing medications

Given its size, the prevention of fraud, waste, and abuse in a taxpayer-funded program like Tricare is paramount. To that end, ESI must adhere to an array of federal and state laws, regulations, and contract terms to ensure a careful and efficient medication delivery program. These mandates require ESI to take steps to prevent, detect, and correct fraud, waste, and abuse, 3-ER-347, ¶ 25 (citing 32 C.F.R. § 199.21 (2018)), including "**flagrant and persistent overutilization of services** without proper regard for … medical needs, or the physician's orders," 3-ER-347, ¶ 26 (citing 32 C.F.R. § 199.9(c)(5) (2020)), and billing for services that would be covered except for "*the frequency*" of the services. 32 C.F.R. § 199.9(c)(2), (5)

(2020); 32 C.F.R. § 199.21 (2018) (emphasis added); 3-ER-347, ¶¶ 25-27. Pharmacy regulations applicable to ESI's Arizona based mail-order pharmacy further require ESI to dispense medications "*consisten[t] with [the] prescription order*," including "[*t*]*he frequency of refills*." Ariz. Admin. Code § R4-23-402(A) (5), (10), (11) (emphasis added); 3-ER-347-48, ¶¶ 30-32.

The contracts between ESI and DHA (the "TPharm's") impose similar requirements on ESI to implement "an effective method for fraud, waste and abuse prevention and detection[,]" such as when a pharmacy bills for "*incorrect quantity or days supply*[.]" 2-ER-205 (Exh. A, TPharm4, § C.11.5.2.1); 2-ER-208 (Exh. B, TPharm2, § C.5.14.2) (emphasis added).

2. Despite these prohibitions, ESI's schemed to over-dispense auto-refill prescriptions for all Tricare beneficiaries by manipulating algorithms in its dispensing program, reaping billions

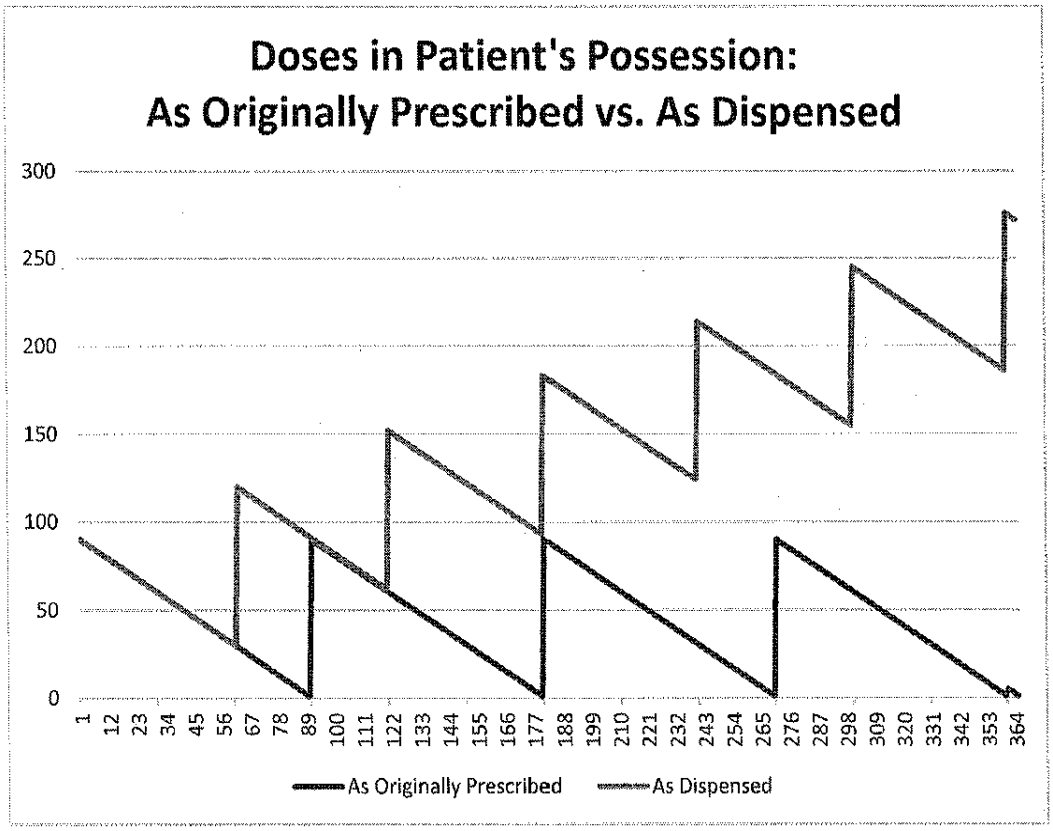
ESI ignored all of these requirements. *See* 3-ER-350-52, ¶¶ 36-46. Instead, motivated by dispensing fees, ESI maximized its dispensing events with an automated shipping program meticulously designed to send unnecessary surpluses of drugs to millions of Tricare beneficiaries. It cost the government billions in unnecessary fees and supplies. 3-ER-339-70, ¶¶ 2-5, 34, 122. No public source—no news article or government report—disclosed this scheme before Relator filed its complaint.

The Pharmacist in Charge (the "PIC") of ESI's Tempe, Arizona mail-order pharmacy – the person responsible for running all pharmacy activities, including compliance with applicable regulations and contractual obligations – had inside knowledge of ESI's fraud. He held that position between 2011 and 2018, and was employed at the facility since 2009. 3-ER-341-54, ¶¶ 7, 54. In that capacity, the PIC, one of the principals of Relator, acquired first-hand knowledge of precisely how ESI organized its auto-ship program to over-charge DoD on a massive scale. Specifically, ESI: 1) enrolled as many Tricare members as possible in the auto-ship program; and 2) calibrated the logic of the auto-ship software so that each prescription would be refilled at the 67% usage date, continuing this cycle indefinitely without regard to the compounding effect of the surplus. 3-ER-339-40, ¶ 3. The PIC observed that the ESI software design team, including senior directors and managers, "deliberately calibrated" the software in this manner both before and after ESI's merger with Medco in 2012. 3-ER-354-55, ¶¶ 54-56.

Through this scheme, ESI essentially operated a refill "pill mill." 3-ER-340-41, ¶ 4. By the end of a year, each Tricare beneficiary received 73% more pills of each maintenance drug on auto-refill than was originally prescribed. That pattern repeated year after year, placing patients' health at risk as they accumulated unneeded refills of expired medications. 3-ER-340-52, ¶¶ 4, 43.

The excess pills dispensed in a single year under ESI's scheme is depicted visually in Relator's complaint as Exhibit 1 (3-ER-340), showing the difference between what ESI dispensed versus what was originally prescribed for a typical 90-day prescription over a 365-day period:

Exhibit 1



Together with Relator's other principals, senior executives of a technology company who also have first-hand knowledge of ESI's member experiences and dispensing practices, the PIC formed the Relator entity and, on June 26, 2019, filed this case to hold ESI accountable, after first disclosing its allegations and evidence to the United States. 2-ER-164-65. The case asserts a single cause of action for

violation of the FCA, 31 U.S.C. § 3729(a)(1)(A)– (B). 3-ER-341-42, ¶ 7. The United States declined to intervene on June 16, 2022. 3-ER-397 (ECF No. 18).

3. ESI's executives deliberately implemented the scheme to impact as many Tricare beneficiaries as possible, and carefully concealed it from the government

Relator alleges that ESI's fraud was a top-down scheme, with executives involved at the highest level. 3-ER-354-68, ¶¶ 55, 113. The PIC Relator "repeatedly raised concerns" with ESI management and employees about the manner in which ESI calibrated its software to dispense excessive medication, but no one at ESI corrected the practice for years, even though ESI's own Vice President of Pharmacy Compliance and other managers shared the PIC's concerns that ESI's "dispensing practices were causing a great deal of medication waste." 3-ER-354-62, ¶¶ 54, 56, 88-89.

Instead, ESI continued to enroll as many Tricare members as it could in the auto-ship program, and refused to recalibrate the logic in its refill algorithm. 3-ER-339-63, ¶¶ 3, 90. For instance, ESI would deliberately confuse patients through ESI's online portal, mislead patients with unclear robocalls, and use other techniques to place and keep patients on the wasteful auto-ship program. 3-ER-357-58, ¶¶ 63-65, 67. ESI aligned employee compensation with the rate at which employees enrolled beneficiaries in the auto-ship program, 3-ER-357-61, ¶¶ 66, 81-82, and contacted prescribers, unbeknownst to, and without authorization from, patients, to

generate new prescriptions and more dispensing fees. 3-ER-351, ¶¶ 41-42. All along, ESI knew beneficiaries were unlikely to "make noise" with ESI or DoD about the over-supply given that DoD, not the patient, was on the hook for most or all of it. 3-ER-361, ¶ 85 (no co-payments were required from members for many Tricare formulary drugs during the relevant period). When conscientious Tricare members *did* complain to ESI, the complaints were ignored. 3-ER-353-63, ¶¶ 49-52, 93.

ESI knew exactly what it was doing, and knew it to be wasteful and wrong, yet continued to specifically target the United States and its military and veteran beneficiaries. Indeed, when ESI acted as the PBM for private insurers, ESI protected its clients' dollars by not permitting refills until later in the usage cycle, and imposed rules on pharmacies prohibiting them from diverging from physicians' prescriptions on days' supply. Thus, ESI routinely penalized or terminated pharmacies for the very sort of behavior that it intentionally and systemically foisted on Tricare. 3-ER-356-70, ¶¶ 59, 72, 116-121.

Moreover, ESI concealed its fraudulent dispensing practices from the government. 3-ER-363-65, ¶¶ 94, 103. ESI knew that intermittent government audits focused more on extreme anomalies as opposed to everyday dispensing patterns. Thus, ESI ensured that its audit responses would not disclose that ESI's dispensing software was calibrated to over-dispense medication. 3-ER-361-64, ¶¶ 84, 100. For example, during a DoD Inspector General ("DOD IG") audit in 2013/2014, the PIC

Relator, who participated in ESI's audit response, observed that ESI made no mention of the calibration of its dispensing software to the government auditors, or of the excessive supply of medication to Tricare beneficiaries. 3-ER-363-64, ¶¶ 94-100. Not surprisingly, the audit report issued by DoD IG stated that while the IG auditors had "attempted to obtain information" on waste resulting from "delivered, unneeded prescription medications," ESI had claimed that it "could not provide [such] data," and thus the auditors were not able to review "patient utilization of their medications." 3-ER-365-66, ¶¶ 101-105. *See also* 3-ER-319-37. Later, ESI again successfully deflected DoD investigators during a separate 2015 review. 3-ER-366-67, ¶¶ 106-109.

ESI had ample opportunity to correct its auto-ship calibration, but consciously chose to extend its fraud for years. 3-ER-354-55, ¶¶ 55, 57. Finally, in late 2017 or early 2018, in an announcement by its then-CEO, ESI changed the calibration of its dispensing software to refill only the first refill at day 60 of a 90-day supply (or day 20 of a 30-day supply), with the second and all subsequent refills shipped on day 90; a simple fix that ESI could have and should have made many years earlier. 3-ER-367, ¶ 110. This change coincided with an increase in Tricare beneficiaries' co-payment responsibility from $0 to $7 per fill effective February 1, 2018, which would likely have prompted increased beneficiary complaints regarding excess medication, thereby tipping off DoD and/or Tricare auditors. *See* 3-ER-368, ¶ 114.

B. Prior "Public Disclosures" Presented by Defendants Did Not Report or Suggest Fraud

In 2013, a publication known as the *Army Times* printed a two-column article titled "*DoD: Mail-order meds program may waste money*." 3-ER-282. The article's purpose was to report on the just-concluded DoD IG audit, the very audit during which Relator alleges ESI deliberately concealed its over-fill practices. 3-ER-363-64, ¶¶ 94-100. As the article reflects, the audit had focused on the savings created by the mail order program, and had concluded "[that DoD IG] had no data on how much medicine is wasted by the program, managed by Express Scripts." 3-ER-282. After suggesting in the article's title that ESI's program "*may* waste money," the article reported several customer complaints about the quality of ESI's mail-order customer service, but just one instance of ESI over-dispensing prescription medications to a retired officer who was interviewed for the article. 3-ER-282 (emphasis added).

The short, 703-word article included the following passages, which comprise the material portions of the piece that were highlighted by the district court:

> *DoD: Mail-order meds program may waste money*
>
> A Pentagon report says the contractor that manages Tricare's pharmacy benefit may be wasting money by continuing to ship drugs to beneficiaries who no longer need them or dispensing 90-day, instead of 30-day, prescriptions.
>
> The report by the Defense Department Inspector General found that Tricare's Mail Order Pharmacy program costs the government and beneficiaries less money than retail stores. But the IG also noted it had

no data on how much medicine is wasted by the program, managed by Express Scripts.

The National Community Pharmacy Association says that information is needed to know whether the home delivery system saves money. And beneficiaries with up to a year's worth of drugs piled in medicine cabinets and linen closets are wondering, as well.

"They ship 90-day supplies after 60 days. By the time I get 12 months into this, I have a nine-month supply of drugs. And I don't dare stop the medications because they'll never get it started again," said retired Air Force Master Sgt. Wayne Stanfield, 70, of South Boston, Va.

Other problems noted by retirees using the Tricare Mail Order Program, or TMOP, include miscommunications with Express Scripts, mix-ups that have left beneficiaries without vital medications and some drugs being out of stock.

The IG found that between April and June 2012, TMOP saved the Pentagon nearly 17 percent over Tricare's retail pharmacy option: $399 million versus nearly $466 million at retail stores, according to the Pentagon.

But the analysis did not include such items as contract costs and administrative overhead associated with mail order or retail prescriptions – or data on waste.

Stanfield received four prescriptions by mail, and his wife receives 10. They reluctantly switched to mail order in 2012 when their copayments through retail pharmacies increased to $5 for generics and $12 for brand names.

At first, the refills ran smoothly, Stanfield said. But in early 2013, Express Scripts changed its website customer interface and made it "nearly impossible to reach the company," he said. Emails arrive in his inbox informing him a prescription needs to be renewed, but don't specify the drug's name or the beneficiary. Phone messages are left on his voice mail, also without any names or specific details.

"Why is there this push to make it mandatory when the program is broken? Somebody needs to look at Express Scripts. They are making

> a fortune off the government, and there are a tremendous amount of retirees who are getting chewed up by the system," Stanfield said.
>
> At press time, Express Scripts had not responded to questions submitted by email or to a telephone request for an interview.

2-ER-282.

Then, in 2014, the Federal Register published comments about a DoD proposed rule to improve Tricare's pharmacy services. Those comments included a submission by an anonymous "professional association" remarking, vaguely and briefly, on "unnecessary waste resulting from auto-ship policies . . . ." The comments suggested but did not specify the implementation of "policies to ensure mail order refills are approved and needed . . . ." CHAMPUS/TRICARE: Refills of Maintenance Medications Through Military Treatment Facility Pharmacies or National Mail Order Pharmacy Program, 81 Fed. Reg. 76,307-01, 76,309 (Nov. 2, 2016) (to be codified at 32 C.F.R. pt. 199). In its response to this comment, DoD stated that it "believes [the prescription medication program] is being implemented successfully and without adverse effects on beneficiaries," but did not address the suggestion of unnecessary waste or possible policies to address it. *Id.* All of two sentences are devoted to the issue in the DoD rulemaking, one in the comment, the other in DoD's response.

Neither the *Army Times* article nor the DoD rule disclosed ESI's intentional, fraudulent scheme to over-fill prescriptions; the auto-refill program carefully calibrated by ESI to carry it out; the massive scale of the scheme; ESI's knowledge

that its auto-refill practices were unlawful; that ESI implemented different standards when it acted as PBM; or ESI's active concealment of its practices from the United States, all of which was first alleged in the complaint. *See* 3-ER-338-88, *passim*. In fact, the DoD response suggests that it was unaware of any significant problems.

C. The District Court Dismisses Complaint Based on the Public Disclosure Rule

In response to the complaint, ESI and its parent company, Express Scripts Holding Company ("ESHC"), filed a motion to dismiss asserting, *inter alia*, that Relator's claims are barred by the False Claims Act's "public disclosure" bar based on the *Army Times* article and Federal Register comment.[1] 3-ER-211-337.

On June 16, 2023, the district court granted Defendants' motion (1-ER-002-33), holding that, under the "public disclosure" rubric outlined in the 9th Circuit's *Mateski* decision, the "publicly available information about [ESI's auto-refill prescription practices for Tricare beneficiaries] contained an 'allegation or transaction' of fraud," and that Relator's complaint "was 'based upon' said 'allegations or transaction.'" 1-ER-018-19 (citing *United States ex rel. Mateski v. Raytheon Co.*, 816 F.3d 565, 570 (9th Cir. 2016)).

[1] The district court dismissed ESHC without prejudice, and without objection from Relator, recognizing Relator's reservation of rights to test Defendants' claim in discovery. 1-ER-012, n.4. ESHC has been replaced on the appellate docket by Evernorth Health, Inc. *See* 9th Cir. Dkt. No. 10.

According to the district court, *Mateski*'s "allegations or transactions" test was met because:

> [i]n short, the *Army Times* article and DoD final rule include facts that the [ESI] program auto-ships a 90-day supply every sixty days for at least some prescriptions; that ESI is profiting off its contract with the government and, presumably, even more so because of its auto-ship and premature refill practices; and that the DoD is missing data on "contract costs and administrative overhead" and "waste."

1-ER-021.

To the district court, "'only a small inferential step' is required to conclude [from these sources] that ESI was misrepresenting the number of refills authorized by physicians and needed by Tricare beneficiaries to increase its profits under its contracts with the DoD." 1-ER-023. Yet it was Relator's allegations that filled the gaps in what the district court acknowledged to be an incomplete picture left by these sources: that ESI's scheme involved all prescriptions, not just "some" of them; that the scheme was deliberate not just careless, baked into the refill software's algorithm with specific intent; that ESI *actually* (not just "presumptively") profited massively from its misconduct; and that the "missing data" was deliberately concealed from the government by ESI and, if it had been provided, revealed intentional, widespread fraud. Without these details, the article neither disclosed fraud nor facts from which an inference of fraud could be made.

The district court further held that Relator's complaint was "based upon" the public disclosures under the *Mateski* factors because they were, to the district court,

"substantially similar." While recognizing that "the *Army Times* article and DoD final rule lack the detail contained in Relator's complaint," the district court held that "they ultimately 'are similar in kind, even if slightly less so in degree,'" and "sufficed to put the DoD 'on notice to investigate the fraud before the relator filed his complaint . . . .'" 1-ER-025 (citing *United States ex rel. Solis v. Millenium Pharms., Inc.*, 885 F.3d 623, 627 (9th Cir. 2018) and *Mateski*, 816 F.3d at 574). According to the district court, "because the *Army Times* article and DoD final rule 'pointed to the *specific tactic* of' auto-refilling a full, 90-day supply of medication every 60 days," this was sufficient to "'alert[] the Government to the specific areas of fraud alleged.'" 1-ER-025 (citing *United States ex rel. Sam Jones Co. v. Biotronik Inc.*, No. CV 17-01391 PSG (KSx), 2023 WL 2993409, at *8 (C.D. Cal. Jan. 4, 2023), *appeal docketed*, No. 23-55361 (9th Cir. Apr. 18, 2023), and *Mateski*, 816 F.3d at 579) (emphasis added). In support of this conclusion, however, the district court pointed only to the *Army Times* article's reference to the Air Force officer's individual auto-refill experience, which reported no intentional, widespread *strategy* by ESI—no "*specific tactic*"—to defraud the government at all. 1-ER-025 (emphasis added).

The district court then turned to Relator's qualification as an "original source" under the False Claims Act, a designation that allows a relator's complaint to proceed even in the face of a public disclosure. 31 U.S.C. § 3730(e)(4)(A). For the

post-2009 period covering the vast majority of Relator's complaint, the district court recognized, correctly, that the 2010 amendments to the FCA removed the "direct" knowledge requirement of the old version, thus "appear[ing] to broaden the exception [to] permit a relator to qualify as an 'original source' of information even if that information was obtained indirectly." 1-ER-029 (citing *United States ex rel. Fryberger v. Kiewit Pac. Co.*, 41 F. Supp. 3d 796, 807 (N.D. Cal. 2014)). Despite this broadening, the district court held that Relator *still* failed to qualify as an original source because "Relator's complaint does not materially add to the public disclosures." 1-ER-030 (citing *United States ex rel. Sanches v. City of Crescent City*, No. C 08-05663 MEJ, 2010 WL 4696835, at *6 (N.D. Cal. Nov. 10, 2010)). The district court held that, "'[a]t most, [Relator's] allegations add detail about the precise methodology [ESI] used' to perpetuate the alleged auto-refilling fraud," 1-ER-031 (citing *United States ex rel. Calva v. Impac Secured Assets Corp.*, No. SACV 16-1983 JVS (JCGx), 2018 WL 6016152, at *8 (C.D. Cal. June 12, 2018)), and that Relator's unique allegations that ESI covered up the fraud did not "materially add to the core fraud allegations themselves, which already were publicly disclosed." 1-ER-032.

In so holding, the district court ignored its own findings that "the Complaint clearly provides a greater amount of detail than the *Army Times* article and DoD final rule," and that the PIC Relator had "independent knowledge of the alleged fraud …

years before the *Army Times* article was published." 1-ER-031-32, n.9. In effect, once the district court found a public disclosure, it foreclosed Relator from qualifying as an original source. Under the district court's logic, virtually no relator, regardless of the extent and independence of its knowledge and its additions to the existing public information, can qualify as an original source if the "core fraud allegations" were previously disclosed, an interpretation that reads the "original source" exception out of the FCA.

In a long footnote, the district court further noted that "Relator may well have qualified as an original source had it—or its members—blown the whistle more promptly," suggesting that Relator and its members were not "brave" enough to earn a *qui tam* award because they waited to file suit until after the PIC Relator had left his position at ESI. 1-ER-032, n.9. To the extent the district court was suggesting that a relator's qualification as original source depends on how promptly it has come forward, rather than on the materiality of the additional information it has come forward with, it cited no authority for that proposition.

For the limited portion of Relator's complaint relating to the time period before the 2009 amendments to the FCA's original source rule, the district court held that Relator is barred from "original source" status because it was not formed until just prior to, and for the purpose of, filing the case. 1-ER-028 (holding that the knowledge of Relator's principals is not imputed to the Relator itself to satisfy the

"direct" knowledge requirement in the 1986 version of the FCA). In reaching this conclusion, the district court relied solely on outlier cases from the Fifth and Tenth Circuits that are inconsistent with this Circuit's jurisprudence and other circuits in analogous contexts, where the knowledge of principals *is* imputed directly to their organizations. *See* 1-ER-026-28; *infra* at Argument, § II(B).

SUMMARY OF ARGUMENT

The dismissal of Relator's complaint on public disclosure grounds constitutes reversible error for two reasons. The district court's first error was in holding that the short 2013 *Army Times* article, together with the brief notice-and-comment exchange in the 2014 DoD rule, contained enough information about ESI's fraudulent conduct to constitute a public disclosure that bars Relator's claims. Neither the article nor the DoD rule revealed a "direct claim of fraud," or showed a "combination of . . . 'a misrepresented state of facts and a true state of facts'" from which to infer fraud, as opposed to mere non-deliberate waste. *Mateski*, 816 F.3d at 570-71 (citations omitted).

The district court's second error was in finding that Relator was not an "original source" because Relator did not materially add to the publicly disclosed information. The district court held that a single example of over-filled prescriptions, and general suggestions of waste in the program, in two sources was enough information from which to infer fraud. But Relator added information that converted

any inference into direct evidence. That information included, among other allegations, how ESI deliberately programmed its software to over-fill on a massive scale, the specific ESI personnel involved in that effort, how the scheme extended well beyond just a few Tricare beneficiaries to ESI's entire program, and how ESI covered it up. These were not background details, but rather perfect examples of "material additions" to qualify Relator as an original source, including direct evidence of scienter that the public sources entirely lacked. Relator's allegations certainly "add[ed] value to what the government already knew." *United States ex rel. Hastings v. Wells Fargo Bank, NA, Inc.*, 656 F. App'x 328, 331-32 (9th Cir. 2016). Indeed, the district court established a standard for the "materially add" test that is virtually impossible to meet, effectively eliminating the original source exception for any relator that brings suit after the "core fraud" has been publicly disclosed.

The district court compounded the error in its original source analysis further by appearing to consider, without any justification, Relator's purported delay in bringing suit. Such delay is irrelevant, untrue, and unfair to Relator and its members, who bravely came forward at substantial risk to inform the government of ESI's fraud.

The district court further erred in disqualifying Relator as an original source under the 1986 version of the FCA, a holding impacting a much smaller portion of

Relator's claims. To the extent "direct" knowledge of fraud was required under the old statute, Relator, a limited liability company formed by its members for the specific purpose of pursuing this complaint, was vested with the direct knowledge of its members.

In sum, this case is not even close to the small "subset" of "parasitic" or "downright harmful" lawsuits that Congress sought to "stifl[e]" with the public disclosure rule. *See Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 294-95, 298-99 (2010). On the contrary, Relator's complaint clearly "strengthen[ed] the Government's hand in fighting false claims," *id.* at 298 (citation omitted), by providing the very first direct allegations of ESI's scheme, and was the only source to have disclosed ESI's intent, among many other allegations found nowhere in the *Army Times* article or DoD rule. This should have qualified Relator as an original source exempt from the public disclosure rule, even if the rule otherwise applied.

STANDARD OF REVIEW

To determine whether the district court improperly dismissed Relator's complaint based on the public disclosure bar, this Court "review[s] the district court's ruling on a motion to dismiss an FCA action *de novo*," a standard that applies to all of Relator's arguments on appeal. *Silbersher v. Valeant Pharms. Int'l, Inc.*, 76 F.4th 843, 852 (9th Cir. 2023) (citing *United States v. Allergan, Inc.*, 46 F.4th 991, 996

(9th Cir. 2022)). *See also Mateski*, 816 F.3d at 568-69 ("[w]hether a particular disclosure triggers the public disclosure bar is a mixed question of law and fact that we review de novo"). In this case, the facts are not disputed—*i.e.*, the language contained in the alleged public disclosures, and the sources that printed that language, are undisputed. Rather, the issue is the district court's interpretation of that language through the framework of the FCA, review of which is governed by the *de novo* standard. *See id.*

To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the primary basis for ESI's motion below, a complaint must allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim "has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 678. *See also United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 991 (9th Cir. 2011). Similarly, to the extent that ESI's motion to dismiss invoked Fed. R. Civ. P. 12(b)(1) to assert a jurisdictional defect under the 1986 version of the FCA's public disclosure rule, courts are instructed to resolve such a challenge "'as [they] would a motion to

dismiss under Rule 12(b)(6).'" 1-ER-010 (quoting *Leite v. Crane Co.*, 749 F.3d 1117, 1121 (9th Cir. 2014)).[2]

As the district court correctly held, courts "must apply the version of the FCA in effect at the time of the alleged fraudulent conduct[.]" 2-ER-132. Two versions of the FCA are relevant in this case given that the fraudulent conduct alleged by Relator spanned from 2009 to approximately 2018: the pre-2010 version (also known as the 1986 version), 31 U.S.C. § 3730(e)(4)(A)-(B) (1986), and the 2010 version (also referred to as the "modern" version), passed into law through the Patient Protection and Affordable Care Act. 31 U.S.C. § 3730(e)(4)(A)-(B) (Mar. 23, 2010). *See Graham Cnty.*, 559 U.S. at 283 n.1. The 2010 amendments to the FCA became effective on March 23, 2010, and do not apply retroactively to conduct that occurred before their effective date. *See Graham*, 559 U.S. at 283 n.1.

Because Relator filed its complaint in June 2019, and the effective FCA statute of limitations here is ten years, 31 U.S.C. § 3731(b)(2), the 1986 version of the FCA applies in this case only to false claims submitted by ESI from June 2009 (the inception of the limitations period) to March 23, 2010 (when the 2010 amendments went into effect). The vast remainder of Relator's claims relating to

[2] An FCA complaint also must satisfy the heightened pleading standard of Fed. R. Civ. P. 9(b). *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998-99 (9th Cir. 2010). Rule 9(b) is not relevant to a public disclosure defense, however; the district court was correct to not base its decision on that standard.

ESI's misconduct from March 24, 2010 until it finally ended its fraudulent program in late 2017 or early 2018, *see* 3-ER-367, ¶ 110, is governed by the FCA's public disclosure rule under the 2010 amendment. *See* 1-ER-016.

ARGUMENT

I. THE DISTRICT COURT ERRED IN FINDING THAT RELATOR'S ALLEGATIONS WERE PUBLICLY DISCLOSED

Under the FCA's public disclosure rule, a court "shall dismiss an action or claim … if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . ," unless the relator is an "original source of the information." 31 U.S.C. § 3730(e)(4)(A). As the district court held, "'[u]nder both versions of the public disclosure bar, § 3730(e)(4) involves a two-step inquiry.'" 1-ER-018 (quoting *Calva*, 2018 WL 6016152, at *3). "'First, the Court must determine whether there was a prior 'public disclosure' of the allegations or transactions underlying the qui tam suit through one of the enumerated sources.'" *Id.* (citing 31 U.S.C. § 3730(e)(4)(A) (1986 & 2010 versions)). "'If there has been a public disclosure, the Court must then determine whether the relator is an 'original source' within the meaning of the statute.'" *Id.* (citing 31 U.S.C. § 3730(e)(4)(A) (1986 & 2010 versions)).

As for step one, "[p]ublic disclosure under either version of the statute requires that 'three things are true: (1) the disclosure at issue occurred through one of the channels specified in the statute; (2) the disclosure was 'public'; and (3) the

relator's action is 'based upon' the allegations or transactions publicly disclosed.'" 1-ER-018 (quoting *Mateski*, 816 F.3d at 570; *accord Allergan*, 46 F.4th at 996.

Since there is no dispute that the *Army Times* article and DoD rule are "channels" specified in the FCA, the dispute on public disclosure here focuses on "whether Relator's Complaint is 'based upon' the 'allegations or transactions' publicly disclosed through these sources." 1-ER-018. "This depends on: (A) whether the publicly available information about [ESI's auto-refill prescription practices for Tricare beneficiaries] contained an 'allegation or transaction' of fraud; and, if so, (B) whether [Relator]'s Complaint was 'based upon' said 'allegation or transaction.'" 1-ER-018-19 (quoting *Mateski*, 816 F.3d at 570). As *Mateski* stated, while "[t]he False Claims Act's public disclosure bar uses the terms 'allegations' and 'transactions' without defining either term[,] . . . [c]ourts have interpreted 'allegation' to refer to a direct claim of fraud, and 'transaction' to refer to facts from which fraud can be inferred." 816 F.3d at 570-71 (citation omitted).

Neither purported source relied on by the district court made a "direct claim of fraud," or showed a "combination of . . . a misrepresented state of facts and a true state of facts" from which to infer fraud substantially similar to that alleged in the complaint. That is, neither source, nor both sources together, disclosed the same "allegations or transactions" upon which Relator based its complaint. It was thus

error for the district court to find that they constitute a public disclosure that bars the complaint.

A. The *Army Times* Article and Federal Register Comment Did Not Disclose or Infer Fraud so as to Constitute "Allegations or Transactions" Under the Public Disclosure Rule

In *Mateski*, this Court clarified that "[a]n allegation of fraud is an explicit accusation of wrongdoing. A transaction warranting an inference of fraud is one that is composed of a misrepresented state of facts plus the actual state of facts." *Mateski*, 816 F.3d at 571 (citing 31 U.S.C. § 3730(e)(4) (A)). Further expanding, the Court explained:

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.
>
> We have further explained that, "in a fraud case, X and Y inevitably stand for but two elements: 'a misrepresented state of facts and a true state of facts.'" "[I]n order to invoke the jurisdictional bar, a defendant must show 'that the transaction ... [is] one in which a set of misrepresented facts has been submitted to the government.'"

Id. (citing *United States ex rel. Found. Aiding the Elderly v. Horizon W. Inc.*, 265 F.3d 1011, 1015-16 *amended by* 275 F.3d 1189 (9th Cir. 2001), and *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)).[3]

[3] The parties and the district court agreed that the "allegations or transactions" test is basically the same under both the 1986 and 2010 versions of the FCA. *See* 2-ER-122 ("the test under each version is substantively identical"); 2-ER-107; 1-ER-016-

1. The district court misapplied the "allegations or transactions" test

In its discussion of the *Army Times* article, the district court primarily focused on the article's reporting of one retired officer's singular experience receiving 90-day medication refills every 60 days. *See* 1-ER-020-21 (quoting retired Air Force Master Sgt. as complaining that he received "90-day supplies after 60 days" and had a "nine-month supply of drugs" after a year that he apparently kept "piled in medicine cabinets and linen closets"). These passages, however, reflect the *Army Times'* interview of a single retired service member about his individual, anecdotal experience with the quality of ESI's auto-refill program. The remainder of the article turns to other examples of poor customer experiences, and notably disclaims any findings on overall waste in the program by DoD. *See* 3-ER-282.

A quote attributed to the retired officer suggests that "[s]omeone … look at Express Scripts," which is "making a fortune off the government." 3-ER-282. The retired officer's chief frustration, it appears, was his inability to talk to a live customer service agent to get the over-supply of medications to stop, a problem that

17. Pursuant to the 1986 version of the FCA, courts do not have jurisdiction to hear claims if they are "based upon the public disclosure of *allegations or transactions*" already published in public sources. 31 U.S.C. § 3730(e)(4)(A) (1986) (emphasis added). Under the 2010 version, courts can dismiss claims "if substantially the same *allegations or transactions* as alleged in the action or claim were publicly disclosed" in (a narrower list of) public sources. 31 U.S.C. § 3730(e)(4)(A)(2010) (emphasis added).

he suggested was caused by a change to ESI's "website customer interface" making it "nearly impossible to reach the company." 3-ER-282. These passages do not disclose or suggest fraud, only that ESI, which is paid handsomely pursuant to its contract with DoD, may be under-performing on its contractual commitments by automating its customer service interface, making refill mistakes like he described difficult to remedy.

Even if the *Army Times* article *could* be read as using the Air Force officer as a representative rather than a unique example, the article at most reported that some Tricare beneficiaries (but apparently very few, given the 92% satisfaction rate reported in the article) had less-than-optimal experiences with ESI's services, and believed that ESI's performance had fallen below expectations to justify its high, contract-based compensation. Even the district court recognized these limitations. *See* 1-ER-021 (noting that the article referred only to "at least some" 90-day prescriptions filled every 60 days).

The comments in the Federal Register referenced by Defendants disclosed even less than the *Army Times* article, and thus are even further from the sort of "public disclosure" that can bar the complaint. The anonymous professional association's comments and suggestions were simply about unspecified auto-ship policies, not fraud of any kind, and certainly not to the degree or in the nature alleged in the complaint. Like the *Army Times* article, the comments did not assert that ESI

was intentionally wasteful, or in what way. Without a "direct claim of fraud," neither the Federal Register nor the Army Times article publicly disclosed the same "allegations" alleged in the complaint. *Mateski*, 816 F.3d at 571.

Nor did the *Army Times* article or DoD rule disclose the same "transactions" referred to in the complaint. In fact, there is no "X" at all in the DoD comments, *i.e.*, the misrepresented state of facts, and no allegation that ESI conspired to fraudulently increase federal reimbursements by calibrating its pharmacy dispensing software unlawfully, or that it applied this calibration universally to all Tricare members. Without these detailed "transactions," the *Army Times* article cannot bar the complaint either, because the article did not show the "set of misrepresented facts [that] has been submitted to the government" (the "X") in combination with the "true state of facts" (the "Y") such that fraud could be inferred (the "Z"). *Mateski*, 816 F.3d at 571.

These specific transactions, found only in the complaint, include the existence, extent, and methods of ESI's fraudulent scheme. There is no disclosure in the *Army Times* article, for example, that ESI calibrated the logic of its pharmacy dispensing software to systematically over-supply prescription refills, let alone that the single retired officer's experience was anything beyond a one-off blip in a system that was prone to errors (according to the article). On the contrary, the *Army Times* article includes contradictory allegations—that in some instances, ESI did not ship

a surplus of medication, but instead notified patients that it was "out of stock" of medications, forcing a particular Retired Navy Chief Petty Officer "to purchase the drugs locally at a much higher price." *See* 3-ER-282. The article did not disclose ESI's cover-up of its scheme during DoD audits, including during the very DoD IG audit that the article reported about. 3-ER-363-66 ¶¶ 94-105.

In the words of *Mateski*, "[a]llowing a public document describing 'problems'—or even some generalized fraud . . . to bar all FCA suits identifying specific instances of fraud . . . would deprive the Government of information that could lead to recovery of misspent Government funds and prevention of further fraud." *Mateski*, 816 F.3d at 577.

This Court most recently examined the FCA's public disclosure rule in *Silbersher*, reversing the district court's dismissal of the relator's FCA case against drug manufacturers on public disclosure grounds. *Silbersher*, 76 F.4th at 847. There, among the public sources at issue was a news article that reported that patent claims asserted by the defendant were "obvious," but "[did] not disclose—nor even imply—that Valeant *knowingly* withheld information . . ." from its claims, as the relator alleged. *Id.* at 857 (emphasis added). This Court allowed the relator's case to proceed because, even though the prior disclosures "each contain[ed] a piece of the puzzle, [] none show[ed] the full picture.":

> [N]o public disclosure here, individually or in combination, establishes facts from which fraud could be inferred. It is the combination of

> disclosures and conduct alleged in Silbersher's complaint that bring together the constituent elements of fraud.
>
> We therefore determine that the public disclosure bar is not triggered here.

Id. at 857-58.

The same is true of Relator's allegations here. The *Army Times* and DoD rule contain, at best, "pieces of the puzzle" but they are—at the very minimum—missing four critical pieces of the full picture: the existence of an actual scheme, as opposed to occasional customer service fumbles; its scope, involving all automatic refills in ESI's massive mail order program, not just one or "some" of them; ESI's specific intent, including its deliberate efforts to develop and implement software algorithms to over-dispense, and its purposeful efforts to hide its algorithms from government audits; and the particular method by which the scheme was perpetrated over multiple iterations of the software.

Ironically, during the hearing below and in supplemental briefing, ESI highlighted the district court's opinion in *Silbersher* as supportive of its position favoring application of the public disclosure bar. 2-ER-076-77; 2-ER-045-47. That decision's reversal by this Court, employing logic equally applicable here, not only negates ESI's arguments, but the district court's decision supporting them.

2. The district court misinterpreted "allegations or transactions" precedent

In ruling that the *Army Times* article contained "allegations or transactions" that rendered it a public disclosure, the district court also relied heavily on *Sam Jones*, 2023 WL 2993409. But the *Sam Jones* decision, which is currently on appeal, generally supports Relator's position, not ESI's. The district court in *Sam Jones* held that a prior *New York Times* exposé that reported, in detail, on defendant's fraudulent practices, including a Department of Justice investigation into them, barred the case under the public disclosure rule. *Id.* at *6. There is a clear and important distinction between the explosive *NYT* article there detailing *important elements of the fraud* as compared to the limited *Army Times* article and DoD rule here alleging, at most, *negligence, mistakes, or customer service errors constituting potential contract breaches* (not fraud). Within that context, the court held that there was "only a small inferential step" required to get to an express allegation of fraud. *Sam Jones*, 2023 WL 2993409 at *7.

Applying Ninth Circuit law, the district court in *Sam Jones* made clear, however, that merely putting the government "on the trail" (*id.* at *9) to initiate an investigation into potential contract or legal breaches is insufficient to qualify as a public disclosure; *fraud* must be alleged or implied in the public source to justify the bar. *Id*. at *5 ("'If the fraud allegations [] are disclosed, the bar applies,' and '[i]f enough of the underlying facts making up the elements of fraud are disclosed, the

bar applies.") (quoting *Amphastar Pharms. Inc. v. Aventis Pharma SA*, 856 F.3d 696, 703-04 (9th Cir. 2017)). Putting the government "on notice to investigate" can suffice, but only if the prior disclosure alleged or implied "the fraud." *Sam Jones*, 2023 WL 2993409, at *5 (quoting *Solis*, 885 F.3d at 626).

In contrast, as the complaint states, "[t]his case concerns the flagrant and persistent over-dispensing of prescription drugs to millions of patients by Express Scripts . . ." through ESI's intentional, improper calibration of its auto-refill program. *See* 3-ER-339-41, ¶¶ 1-5. Nothing of the sort appears in the article or the DoD rule. The mere possibility that ESI "may be wasting money," as the *Army Times* article's headline suggests, is far from a "direct claim of fraud," or even suggestive of one. *Mateski*, 816 F.3d at 570-71. As the complaint alleges, ESI did not just carelessly or negligently ship excess medications to a single veteran officer, or even to "some" beneficiaries (using the district court's characterization). 1-ER-021. It intentionally perpetrated a scheme on the entire United States military, active and inactive; built an entire digital and marketing infrastructure, including software coding, to carry it out; and wrongfully collected "billions of dollars in excessive dispensing fees and drug replacement costs." 3-ER-339-41, ¶¶ 3, 5.

Within this context, far more than "'a small inferential step'" is required to jump from the public sources to an express allegation of fraud, contrary to the district court's ruling. 1-ER-022 (quoting *Sam Jones*, 2023 WL 2993409 at *7). The public

sources here were insufficient under this Circuit's settled law to constitute "allegations" or "transactions" giving rise to a public disclosure.

B. Relator's Complaint Is Not Based Upon, or Substantially the Same As, the Public Sources

Even if the *Army Times* article and DoD rule contained "allegations or transactions," Relator's complaint was not "based upon" them. "[F]or a relator's allegations to be 'based upon' a prior public disclosure, 'the publicly disclosed facts need not be identical with, but only substantially similar to, the relator's allegations.'" *Mateski*, 816 F.3d at 573 (citing *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009), *overruled on other grounds by United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121, 1128 n.6 (9th Cir. 2015); *Malhotra v. Steinberg*, 770 F.3d 853, 858 (9th Cir. 2014)). "[W]hether [a FCA c]omplaint is substantially similar to prior public reports depends on the level of generality at which the comparison is made." *Mateski*, 816 F.3d at 575. This Court has cautioned that "*viewing FCA claims 'at the highest level of generality . . . in order to wipe out qui tam suits that rest on genuinely new and material information is not sound.*'" *Id.* at 577 (quoting *Leveski v. ITT Educ. Servs., Inc.*, 719 F.3d 818, 831 (7th Cir. 2013)). "[A]nother way of thinking about substantial similarity" is to "ask[] whether the Government was on notice to

investigate the fraud before the relator filed his complaint . . . ." *See Mateski*, 816 F.3d at 574.[4]

In applying the "based upon" test, courts in this Circuit have held that "[t]he [public disclosure] bar does not apply where a relator's complaint 'alleges fraud that is different in kind and in degree from the previously disclosed information.'" *United States ex rel. Jahr v. Tetra Tech EC, Inc.*, No. 13-cv-03835-JD, 2022 WL 2317268, at *9 (N.D. Cal. June 28, 2022) (citing *Mateski*, 816 F.3d at 578). "'Conversely, the public disclosure bar does apply where the relator's complaint and the prior disclosure 'are similar in kind, even if slightly less so in degree.'" 1-ER-024 (quoting *Solis*, 885 F.3d at 627). Correctly summarizing the standard, the district court stated: "In other words, complaints that provide 'specific examples' of previously disclosed 'general problems' and 'relators who provide the Government with genuinely new and material information of fraud [should be allowed] to move forward with their *qui tam* suits.'" 1-ER-024 (quoting *Mateski*, 816 F.3d at 578–79).

Contrary to the district court's decision, that is precisely what Relator's complaint does here. Unlike the *Army Times* article and the DoD rule, Relator's

[4] This Court recently confirmed in *Silbersher* that the change in the FCA's public disclosure rule from "based upon" to "substantially the same as" does not require a different substantive analysis. *Silbersher*, 76 F.4th at 855-56 ("Congress re-enacted its prior law in clearer terms by replacing 'based upon' with 'substantially the same as,' leaving our precedent interpreting that phrase undisturbed.") (citing *Allergan*, 46 F.4th at 996 n.5; *Mateski*, 816 F.3d at 570 n.7, 573 n.14).

complaint alleges that ESI did not just over-supply one military veteran, but schemed to over-supply *all* members signed up for mail-order delivery globally, and did so *intentionally* through orchestration by its top executives and execution at every level of its business. 3-ER-338-73, *passim*. *See United States ex rel. Baltazar v. Warden*, 635 F.3d 866, 869 (7th Cir. 2011) (concluding that pre-2010 FCA claims were not "based on" prior disclosures, and post-2010 claims were not "substantially similar" to them, where relator's complaint "supplied vital facts that were not in the public domain: that [defendant] not only was submitting false claims but also was submitting them knowing them to be false, and thus was committing fraud.").

The complaint goes even further. It includes allegations that ESI, on the commercial side of its business when it acted as a PBM, prohibited any other pharmacy from engaging in the same type of wasteful profiteering that it employed systematically under its Tricare contracts with DoD. 3-ER-369, ¶¶ 116-18. It details how ESI actively violated the prescribing orders from physicians, and knowingly broke industry standards to increase its bottom line. *See* 3-ER-338-73, *passim*. It includes allegations that ESI engaged in a cover-up, strategically hiding its oversupply algorithm and practice from the government for years. *See* 3-ER-361-65, ¶¶ 84, 94, 100, 103. None of these allegations are found in the *Army Times* or the DoD rule.

The Ninth Circuit has repeatedly warned of the dangers of allowing generalizations like that found in the DoD rule and isolated disclosures untethered to fraud like those in the *Army Times* article to preclude actions under the FCA via the public disclosure bar. In *Mark ex rel. United States v. Shamir USA, Inc.*, for example, the defendants attempted to raise the public disclosure defense against anti-kickback fraud based on just "one announcement" in which the defendants had vaguely alluded to their rewards-back program and other benefits offered for using their products. No. 20-56280, 2022 WL 327475, at *2 (9th Cir. Feb. 3, 2022). The court found that "the information disseminated was so innocuous that there was no public disclosure of a transaction or allegation of fraud in the first instance, as required under the FCA." *Id*.

The same result is required here, to avoid "the dangers of allowing a generalized description of a program that could give rise to fraud in public documents to prevent the pursuit of legitimate fraud[.]" *Id*. To the extent the *Army Times* article reported an example of over-supplying that might have been part of the overall scheme of fraud, it did so without reporting or implying fraud, the existence of a scheme, or even, in the district court's words, the "'specific tactic'" employed by ESI to overcharge the government. *See* 1-ER-025 (quoting *Sam Jones*, 2023 WL 2993409, at *8). In fact, there was no reporting of a "specific tactic" at all, just examples of customer dissatisfaction and anecdotal mistakes in ESI's program. The

allegations in the complaint are thus "different in kind and in degree from the previously disclosed information." *Jahr*, 2022 WL 2317268, at *9 (applying the 2010 version of the public disclosure rule). *See also Mateski*, 816 F.3d at 567-69 n.7 (applying the 1986 version of the rule, but noting that its analysis would be the same under the 2010 version.).

The district court's decision erred, at the very least, in its unsupported pronouncement that the difference between Relator's allegations and the public sources was only "slightly less so in degree." 1-ER-025. The *Army Times* article simply reported that ESI's mail-order program "may be wasting money," briefly describing a few poor customer experiences, including a single instance of a Tricare recipient who had been over-supplied with medication. *See* 3-ER-282. Likewise, the professional organization's vague comments in the Federal Register regarding "unnecessary waste resulting from auto-ship policies" (81 Fed. Reg. at 76,309), is not substantially the same as the vast, deliberate scheme that Relator has alleged. *See Baltazar*, 635 F.3d at 867 (finding that a publication was not substantially similar to an FCA complaint where it only disclosed "errors [that] may have been caused by negligence rather than fraud[.]"). At most, the prior sources put the government on notice of breach or mistake, not of fraud. This is insufficient to raise a defense under the FCA's public disclosure bar.

The complaint differs from ESI's sources, both in kind and certainly in degree. The district court erred in applying the public disclosure bar to this case.

II. EVEN IF THE PUBLIC DISCLOSURE BAR WERE APPLICABLE, RELATOR QUALIFIES AS AN ORIGINAL SOURCE

Given the glaring differences between the complaint and the prior publications relied on by Defendants, the public disclosure bar is inapplicable. But even if this Court were to agree with the district court that the *Army Times* article and/or the DoD rule contained substantially similar transactions and allegations as the complaint, Relator's case should still survive because Relator is an original source, exempt from the public disclosure defense.

The 2010 amendments, which apply to the vast majority of Relator's case against ESI, changed the original source rule to remove the requirement that original sources have "direct" knowledge of the misconduct. Instead, after the 2010 amendments, an original source must simply have "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions[.]" 31 U.S.C. § 3730(e)(4)(B) (2010). This "app[arent] [] broaden[ing]" of the original source test was recognized by the district court, but then misapplied. *See* 1-ER-029 (citing *Hastings*, 656 F. App'x at 331-32). Despite the district court's ruling, there should be no serious dispute that Relator's complaint materially adds to the brief, vague assertions in Defendants' sources. Under the 2010 version of the rule, Relator

is an original source of its allegations relating to false claims submitted by ESI after March 2010.

Relator has also met the requirements of an original source as to false claims governed by the pre-2010 original source test, which represents a small portion of the claims in this case. Before the 2010 amendments to the FCA, an original source was required to have "*direct* and independent knowledge of the information on which the allegations are based[.]" 31 U.S.C. § 3730(e)(4)(B) (1986) (emphasis added). Relator's knowledge comes directly from its own principals, which meets the requirement of "direct" knowledge under the 1986 rule. *See, e.g., Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1049 (8th Cir. 2002) (under the 1986 version of the rule, corporate relators can have direct knowledge and qualify as original sources; the mere fact that a corporate entity acts through its agents does not change that).

A. Relator's Complaint Satisfies the 2010 Original Source Rule by Providing "Material Additions" to the Public Disclosures

Turning first to the 2010 version of the original source exception that largely governs here, Relator clearly meets the "materially adds" requirement. The detailed, direct allegations of fraud, including specific evidence of ESI's scienter in Relator's complaint, materially add to what the *Army Times* article and the DoD rule disclosed, vaguely and briefly, several years before Relator initiated this case.

With Relator's insights, the complaint did not "provide only background information and details relating to the alleged fraud . . . ." (fraud which the *Army Times* article and DoD rule never directly disclosed and, at most, barely implied); rather, Relator's allegations "add[ed] value to what the government already knew." *Hastings*, 656 F. App'x at 331-32.

1. Relators meet the "materially adds" test when they provide direct allegations of a scheme, or of the defendant's fraudulent intent, lacking in the public disclosure

Although different circuits have interpreted "materially adds" more or less strictly, all agree generally with the following three principles.

First, "the fewer questions the public disclosures answer, the more room there is for a relator's allegations to add material information." *United States ex rel. Reed v. KeyPoint Gov't Sols.*, 923 F.3d 729, 756-57 (10th Cir. 2019). *See also United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 25 (1st Cir. 2009) (relators may provide "different information of the publicly disclosed fraud . . . of great significance," especially when the public disclosures themselves rely on uncertain or unavailable information).

Put another way, a relator who comes forward with direct evidence establishing the existence of a scheme previously only suggested by public sources is generally worthy of original source status. *See United States ex rel. Fadlalla v. DynCorp Int'l LLC*, 402 F. Supp. 3d 162, 185 (D. MD. 2019) ("The Amended

Complaint paints a vivid picture of each Relator's personal experience with the fraud scheme, alleging facts that not only corroborate information publicly disclosed, but that also breathe important life into proving the scheme with admissible evidence.") *See also Fryberger*, 41 F. Supp. 3d at 809 ("The detailed allegations go far beyond the information disclosed in the news reports and present information not discussed in the government investigations.") Under the Third Circuit's useful construct, "[a] relator 'materially adds' to the public disclosures 'when it contributes information...that adds in a significant way to the essential factual background: 'the who, what, when, where and how of the events at issue.'" *Fadlalla*, 402 F. Supp. 3d at 184-85 (quoting *United States ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016)).

Second, a relator who comes forward with evidence of the defendant's fraudulent intent, where the information publicly disclosed is lacking in that critical FCA element, may qualify as an original source on this basis alone. *See Reed*, 923 F.3d at 761 ("[R]egardless of how well defined the fraud allegations are in a qualifying public disclosure, when a relator brings forth knowledge of scienter that is not specifically contained in a qualifying public disclosure it should be presumed to materially add value.") (internal citation omitted). *See also United States ex rel. Kuriyan v. HCSC Ins. Servs. Co.*, No. CIV 16-1148 JB/KK, 2021 WL 5998603, at *42 (D.N.M. Dec. 20, 2021) ("Knowledge of scienter that is not specifically

contained in a qualifying public disclosure" may have the effect of "expanding the scope of the fraud.") (internal citations omitted).

As the Tenth Circuit explained in *Reed*:

> Ms. Reed's allegations of scienter make us especially confident that her allegations regarding KeyPoint's fraudulent TTP practices satisfy the materially-adds standard. False Claims Act "cases often turn on the issue of scienter." Hesch, *supra*, at 1024. Yet, "the government is never in a good position to have direct evidence of guilty knowledge." *Id.* Thus, Ms. Reed's allegations that KeyPoint's investigators and managers tried to *knowingly* cover up the TTP violations amplify the materiality of the underlying allegations of TTP fraud.

923 F.3d at 760-61. *See also United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 213 (1st Cir. 2016) ("We do not rule out the possibility that furnishing information that a particular defendant is acting 'knowingly' (as opposed to negligently) sometimes may suffice as a material addition to information already publicly disclosed.").

Third, "merely because the allegations are substantially the same as a qualifying public disclosure, a relator still qualifies as an original source if she brings something to the table that adds value." *Reed*, 923 F.3d at 757-58 (internal citation omitted). Thus, "the 'materially adds' inquiry must remain conceptually distinct" from the public disclosure inquiry; "otherwise, the original source exception would be rendered nugatory." *Winkelman*, 827 F.3d at 211-12. As the *Reed* court remarked, "[a]fter all, what good is an exception (i.e., the original-source exception) that does not actually except anything?" *Reed*, 923 F.3d at 757 (because the materially-

adds condition "'is designed to be an exception to the public disclosure bar,'" it "'is not meant to block out relators simply because there had been a qualifying public disclosure that contains similar allegations'"). *Id*. (citation omitted). *See also Moore*, 812 F.3d at 306 ("The exception, of course, comes into play only when some facts regarding the allegation or transaction have been publicly disclosed.").

2. The district court ignored Relator's direct evidence of ESI's fraud and intent, and conflated the public disclosure bar with the original source test

The district court's decision disqualifying Relator as an original source under the 2010 FCA directly violates each of these principles. The short *Army Times* article referencing just one example of over-supplying a single retired officer, and a couple of sentences in a DoD rule, are the sort of thin disclosures that leave ample "room" for a relator's allegations to add material information. *Reed*, 923 F.3d at 757. Relator's complaint fills the void not merely with "inferences" of fraud found by the district court in the public sources, but with actual, direct evidence of fraud, "breathing important life" into proving the scheme. *See Fadlalla*, 402 F. Supp. 3d at 185.

Indeed, Relator contributes information "that adds in a significant way to the essential factual background," including unique, material evidence of "the who, what, when, where and how of the events at issue." *Moore*, 812 F.3d at 307:

- *Who*: Relator identifies the specific ESI executives and employees who oversaw the scheme, including the design and implementation of dispensing software containing the fraudulent algorithms. *See* 3-ER-351-368, ¶¶ 41, 87-89, 113-14. None are identified in the public sources.
- *What*: Relator alleges an *actual, deliberate scheme* involving *all* automatic refills in ESI's massive mail order program, 3-ER-338-73, *passim*, not just anecdotal refill errors involving one or even "some" Tricare beneficiaries, or general "waste," as reported in the *Army Times* article and DoD rule.
- *When and Where*: Relator alleges that, "from at least 2009 until approximately 2014," Express Scripts developed and used its own proprietary software calibrated to over-dispense medication according to the improper formula alleged in the complaint at ESI's mail-order pharmacy in Tempe, Arizona. 3-ER-354, ¶ 54. "In 2014, following the merger of Express Scripts and Medco," Relator alleges that ESI rolled out a new dispensing software, called "F-14," that "was deliberately calibrated to carry forward the automatic refill dispensing practice … at all Express Scripts pharmacy locations." 3-ER-354-55, ¶ 55. ESI left this improper calibration in place until late 2017 or early 2018. 3-ER-

365, ¶ 110. None of this information can be found in the public sources, which suggest, if anything, limited short-term problems with "waste" in ESI's program at unspecified ESI location(s).

- *How*: The use of specific software algorithms—not just one iteration, but two—by ESI to effectuate its deliberate scheme is alleged with specificity by Relator, 3-ER-339-55, ¶¶ 3-4, 54-57, yet found nowhere in the public sources. Nor is ESI's careful concealment of its dispensing practices from the government as detailed by Relator, 3-ER-361-67, ¶¶ 83-109, or ESI's practice as PBM of avoiding or penalizing the very overfill practices that it foisted on the government, 3-ER-356-70, ¶¶ 59, 72, 116-121. The public sources reveal none of these details, and no other information, about *how* ESI actually effected its scheme.

Indeed, the complaint adds specific, detailed information and evidence to the public sources about ESI's *specific intent* to defraud the government, deliberately creating and implementing at least two different algorithms to effectuate its scheme, and actively concealing its conduct from the government. 3-ER-354-67, ¶¶ 54-57, 83-109. Relator thus provided direct evidence of ESI's scienter entirely lacking in the public sources. This alone should suffice to meet the "materially adds" test, qualifying Relator as an original source. *See Reed, Winkelman, Baltazar supra*.

Finally, the district court's determination that Relator's allegations were mere "details" that offered "additional color" about a fraud scheme previously disclosed in the public sources violated the third principle by rendering the original source exception "nugatory." *Winkelman*, 827 F.3d at 212. While acknowledging that the *Army Times* article and DoD rule at most "inferred" the existence of a fraud, 1-ER-020, and that "the Complaint clearly provides a greater amount of detail than the Army Times article and DoD final rule," 1-ER-031, the district court "[found] persuasive" ESI's argument that Relator's allegations "'do not materially add to the core fraud allegations themselves, which already were publicly disclosed.'" 1-ER-031-32 (quoting 2-ER-145).

This circular logic effectively eliminated the FCA's original-source exception to the public disclosure rule. Relator was disqualified from being an original source because the district court fixated on its (incorrect) holding that the public sources had already disclosed the "core fraud allegations." 1-ER-031-32. But this is precisely when the original source exception is supposed to "come[] into play." *Moore*, 812 F.3d at 306. Even if Relator's allegations were substantially the same as qualifying public disclosures, it still qualifies as an original source if it "add[ed] value to what the government already knew." *Hastings,* 656 F. App'x at 331-32.

Moreover, all of the cases relied on by the district court on this issue involved public sources that had previously reported, *directly and in detail,* the fraud at issue,

e.g., they contained direct fraud allegations that the relators' allegations added to only incrementally, if at all. For example, in *Sanches*, 2010 WL 4696835, at *8, the case principally relied on by the district court, "misappropriation of [] HUD funds [was] already disclosed in the information section of [a] staff report at an administrative hearing prior to Plaintiff's employment." These were the "same allegations Plaintiff [made] in her FCA claim." *Id*. The court held that "Plaintiff's complaint simply republishes information already publicly disclosed and adds nothing to that disclosure." *Id*.

Similarly, in *Winkelman*, "the public disclosures made it crystal clear that CVS was not providing its HSP prices to Medicaid and, by extension, to Medicare Part D." 827 F.3d at 212. The disclosures also "made it pellucid that CVS was acting deliberately, and that its course of conduct was studied (not merely careless)." *Id*. at 213. The court held that "[o]ffering specific examples of that conduct does not provide any significant new information where the underlying conduct already has been publicly disclosed." *Id.* at 212. *See also Calva*, 2018 WL 6016152, at *8 ("allegations regarding the false and misleading disclosures were already publicly disclosed"). *See also United States ex rel. CKD Project LLC v. Fresenius Med. Care Holdings, Inc.*, 551 F. Supp. 3d 27, 46 (E.D.N.Y. 2021), *aff'd*, 2022 WL 17818587 (2d Cir. Dec. 20, 2022) (relator offered "nothing" to demonstrate its "contributions to the public record").

The district court compounded its error by inexplicably suggesting, in a final footnote, that Relator was disqualified as an original source not because it failed the "materially adds" test, but because it did not file suit until after the PIC Relator had left his job at ESI. 1-ER-032, n.9 ("Relator may well have qualified as an original source had it—or its members—blown the whistle more promptly"). The district court cited no authority tying a relator's original source qualification under the "materially adds" test to when it files suit (*e.g.*, whether before or after the relator or its members leave their insider positions). Instead, the district court relied only on cases offering general observations about how the public-disclosure bar strikes a balance between "rewarding insiders" and discouraging "opportunistic plaintiffs." 1-ER-032, n.9 (citing cases).

Neither this Court nor any other has included "promptness of filing" as an element of the test. On the contrary, it is commonplace for insider relators, like the PIC Relator here, to exhaust their efforts to effect change from within before filing a *qui tam* claim after leaving their companies. "Promptness," or lack thereof, has had no impact on their qualification as original sources through material additions to public disclosures. *See, e.g., Gonzalez v. Planned Parenthood of L.A.*, 392 F. App'x 524, 527 (9th Cir. 2010) (ruling that relator, the chief financial officer of defendant, qualified as an original source of fraud, reversing dismissal on public disclosure grounds; relator had learned of the fraud during his employment but waited over 18

months after he left his position to file a *qui tam* complaint under the FCA). *See also Hartpence*, 792 F.3d at 1122 ("there are two, and only two, requirements in order for a whistleblower to be an 'original source,'" neither of which—notifying the government and direct and independent knowledge under the 1986 version of the rule—includes the promptness with which it pursues its claims).

The district court was unjustified in questioning the "bravery" of Relator and its members. If the district court based its original source ruling on that personal assessment, it only compounded its error. If Relator "may well have qualified as an original source had it … blown the whistle more promptly," and blowing the whistle promptly is not an appropriate consideration, then even the district court appears to have recognized that Relator "may well have qualified as an original source." If so, reversing the district court should be just that simple.

Regardless, Relator's allegations clearly "add[ed] value" to the information that the government "already knew," qualifying it as an original source under the modern version of the rule. *Hastings*, 656 F. App'x at 331-32.[5]

[5] The district court did not reach a second purported basis raised by ESI below against Relator being an original source under the 2010 public-disclosure bar, that "an entity formed solely for the purpose of bringing a *qui tam* lawsuit cannot be an 'original source'" under the 2010 rule. 1-ER-029-30 (citing 2-ER-125). Relator will address this argument more fully if raised by ESI as a separate basis for affirming the district court's decision under the 2010 FCA. For now, as detailed in the complaint, Relator notes that its principals learned of ESI's scheme independent of the *Army Times* article or DoD rule, through their own personal experiences, including those of the PIC Relator, who worked as an employee of ESI and saw the

B. The District Court Erred in Ruling That LLCs Like Relator Cannot Be Original Sources Under the 1986 Version of the FCA

With regard to the limited number of pre-2010 false claims at issue in this case, the 1986 version of the original source rule governs. That version of the rule turns not on whether the relator "materially added" information like the modern rule, but on whether the relator had "direct" knowledge of the fraud. Summarizing the 1986 version of the rule, this Court held in *Amphastar* that, "[t]o prove 'direct' knowledge, [the relator] 'must show that [it] had firsthand knowledge of the alleged fraud, and that [it] obtained this knowledge through [its] own labor unmediated by anything else.'" *See Amphastar*, 856 F.3d at 705 (quoting *United States v. Alcan Elec & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999).

Under that standard, Relator *did* have direct knowledge, satisfying the 1986 test, too. Relator acquired its knowledge directly from its own members, including the PIC Relator, who indisputably had "firsthand knowledge" of ESI's fraud during his years working at ESI as its pharmacist in charge of its main Tempe facility. *See* 1-ER-341-68, ¶¶ 7, 54, 56, 66, 88, 89, 92, 93, 96, 97, 100, 103, 107, 108, 113 (specifying the direct knowledge of ESI's fraud that Relator possesses through its principals, including the PIC Relator).

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fraud first-hand. 3-ER-341-54, ¶¶ 7, 54. This "independent" knowledge is all that is required under the 2010 public disclosure rule; it is also sufficient under the 1986 rule, as demonstrated in the next section, *infra* Argument, § II(B).

Nevertheless, the district court ruled, incorrectly, that where the relator is a business entity alleging facts within the knowledge of its principals "collected . . . before its formation," it cannot be an original source under the 1986 rule. 1-ER-028. This is simply incorrect.

First, "[n]o courts have held that corporations responsible for the discovery of information cannot have 'direct knowledge' because they have to act through agents." *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 801 (E.D. La. 2009) (citation omitted). The Eighth Circuit has held that "[t]hough organizations must, of course, act through agents, this does not render their knowledge parasitical or their agency 'intervening' in the sense of interrupting the causal connection between the corporation's efforts and the knowledge." *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1049 ("corporate plaintiffs have been held to have direct knowledge making them an original source.").

Limited liability companies like Relator are legally capable under the law of "knowing" facts, and their status as separate entities from their member-managers does not change that, as courts in this Circuit have held. *See e.g. United States ex rel. STF, LLC v. Vibrant Am., LLC*, No. 16-cv-02487-JCS, 2020 WL 4818706, at *19 (N.D. Cal. Aug. 19, 2020) (LLC relator adequately pleaded scienter by alleging that the defendant LLC "knows this strategy is illegal[.]"). The scienter element of the FCA itself provides that any "person" who "knowingly" commits a violation is

liable, 31 U.S.C. § 3729(a), where "person" is defined by the U.S. Code to "include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." 1 U.S.C. § 1.

Second, the mere fact that Relator, through its principals, authorized the filing of this lawsuit based on information learned by those same principals before they formed Relator as an LLC, does not somehow change Relator's knowledge from "direct" to "indirect." Reference to the law of agency quickly negates the concept. *See* Restatement (Third) of Agency, "Imputation of Notice of Fact to Principal," § 5.03(e) (2006) ("When an agent is aware of a fact at the time of taking authorized action on behalf of a principal and the fact is material to the agent's duties to the principal, notice of the fact is imputed to the principal although the agent learned the fact prior to the agent's relationship with the principal, whether through formal education, prior work, or otherwise.").

The two out-of-circuit cases relied on by the district court are inapposite. 1-ER-027-28. In *United States ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548 (10th Cir. 1992), the court, applying the 1986 version of the original source rule, considered the information that the relator had acquired after its formation—consisting of investigative materials like unverified third-party statements and interview summaries—and characterized it as insufficiently direct and independent. 971 F.2d at 554. The court did *not* reason that the relator failed to qualify as an

original source *because* the relator had been formed shortly before it filed its FCA complaint. *Id*. Similarly, in *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995), the court ruled against the specially-formed LLC relator on original source primarily because the information that it acquired from its members was, like the relator's in *Precision Co.*, "'weak, informal, and strikingly redundant.'" *Fed. Recovery Servs.*, 72 F.3d at 451-52.

To the extent that these two cases actually stand for the proposition for which the district court cited them, they are outliers and inconsistent with better-reasoned cases that corporations are vested with the direct knowledge of their principals under the original source exception, no matter when that knowledge was acquired. *See supra Branch Consultants, Springfield Terminal, Minn. Ass'n of Nurse Anesthetists.* Specially-formed entity relators are not disqualified by law from being original sources under the 1986 version of the FCA. The district court erred in being the first to so hold in this Circuit.

In its post-hearing supplemental brief below, ESI argued that the district court opinion in *Sam Jones*, currently on appeal in this Court, supports a separate, but similar, basis for disqualification under the 1986 original source rule—that an entity relator, formed just prior to filing suit, can never have knowledge "independent" of a prior, public disclosure to satisfy the rule because entity relators "know" nothing until they are formed. *See* 2-ER-048 (citing *Sam Jones*, 2023 WL 2993409, at *9).

But *Sam Jones* does not support ESI's baseless contention, which the district court, in any event, did not adopt. The *Sam Jones* court had exactly the right case to embrace ESI's argument—it was confronting an original source issue involving an entity relator specially formed just prior to bringing the action. But the court looked solely to the knowledge of the LLC relator's *principals*, not that of the LLC relator itself, and the timing of their obtaining that knowledge, to decide the question. *See Sam Jones*, 2023 WL 2993409, at *8 ("Relator . . . fails to plead allegations showing it knew about the fraud *before* the 2011 article [i.e., the public disclosure] was published.").

Here, unlike in *Sam Jones*, Relator's information pre-dates any public disclosure, as the PIC Relator, employed by ESI from 2009 through 2018, first discovered ESI's fraud well prior to the December 2013 *Army Times* article and November 2016 DoD rule. *See, e.g.,* 3-ER-341-66, ¶¶ 7, 54, 94-105. Under the logic in *Sam Jones*, the pre-disclosure knowledge of Relator's principals is more than sufficient to satisfy the original source test's requirement of "independent" knowledge (under both versions of the FCA).

ESI should not escape liability for its brazen fraud on the United States, or any portion of it, based solely on the date that Relator happened to file its articles of organization, or the timing of when Relator acquired knowledge from its principals.

Under the 1986 version of the original source rule, Relator qualifies as an original source, with direct knowledge of ESI's fraudulent scheme.

CONCLUSION

For the reasons set forth herein, the district court's decision dismissing Relator's complaint on the basis of the False Claims Act's public disclosure rule constitutes reversible error.[6] The district court's order granting the motion to dismiss, and final order and judgment effecting that order, should be reversed, and the case should be remanded so that it can proceed.

[6] Because the district court's dismissal was based solely on its narrow discussion of public disclosure, Relator has confined its discussion in this opening brief to the district court's rationale on that issue. To the extent ESI seeks affirmance on any ground not articulated therein, Relator reserves discussion of such ground(s) to its reply brief.

Dated: October 30, 2023

Respectfully submitted,

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STATEMENT OF RELATED CASES

Plaintiff-Relator-Appellant is not aware of any related cases that are currently pending in this Court.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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CERTIFICATE OF SERVICE

Attorney Roger A. Lewis certifies that on October 30, 2023, the **PLAINTIFF-RELATOR-APPELLANT'S OPENING BRIEF** was filed electronically with the Ninth Circuit Court of Appeals which in turn will electronically serve notification of such filing to all counsel of record.

Dated: October 30, 2023

/s/ Roger A. Lewis
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Attorney for Plaintiff-Relator-Appellant, 3729, LLC

ADDENDUM

Addendum

United States Code Annotated
Title 31. Money and Finance (Refs & Annos)
Subtitle III. Financial Management
Chapter 37. Claims (Refs & Annos)
Subchapter III. Claims Against the United States Government (Refs & Annos)

This section has been updated. Click here for the updated version.

31 U.S.C.A. § 3730

§ 3730. Civil actions for false claims

Effective: March 23, 2010 to July 21, 2010

(a) Responsibilities of the Attorney General.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. [1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [2] Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) Certain actions barred.--(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--

(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;

(ii) in a congressional, Government[2] Accountability Office, or other Federal report, hearing, audit, or investigation; or

(iii) from the news media,

unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

(f) Government not liable for certain expenses.--The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) Fees and expenses to prevailing defendant.--In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) Relief from retaliatory actions.--

(1) In general.--Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any

other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor, or agent or associated others in furtherance of other efforts to stop 1 or more violations of this subchapter.

(2) Relief.--Relief under paragraph (1) shall include reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An action under this subsection may be brought in the appropriate district court of the United States for the relief provided in this subsection.

CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978; Pub.L. 99-562, §§ 3, 4, Oct. 27, 1986, 100 Stat. 3154, 3157; Pub.L. 100-700, § 9, Nov. 19, 1988, 102 Stat. 4638; Pub.L. 101-280, § 10(a), May 4, 1990, 104 Stat. 162; Pub.L. 103-272, § 4(f)(1)(P), July 5, 1994, 108 Stat. 1362; Pub.L. 111-21, § 4(d), May 20, 2009, 123 Stat. 1624; Pub.L. 111-148, Title X, § 10104(j)(2), Mar. 23, 2010, 124 Stat. 901.)

Footnotes

1 See, now, Rule 4(i) of the Federal Rules of Civil Procedure.

2 So in original. Probably should be “General”.

31 U.S.C.A. § 3730, 31 USCA § 3730
Current through P.L. 118-19. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 31. Money and Finance (Refs & Annos)
Subtitle III. Financial Management
Chapter 37. Claims (Refs & Annos)
Subchapter III. Claims Against the United States Government (Refs & Annos)

This section has been updated. Click here for the updated version.

31 U.S.C.A. § 3730

§ 3730. Civil actions for false claims

(a) Responsibilities of the Attorney General.--The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.--(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. [1] The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.--(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.--(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [2] Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

(e) Certain actions barred.--(1) No court shall have jurisdiction over an action brought by a former or present member of the armed forces under subsection (b) of this section against a member of the armed forces arising out of such person's service in the armed forces.

(2)(A) No court shall have jurisdiction over an action brought under subsection (b) against a Member of Congress, a member of the judiciary, or a senior executive branch official if the action is based on evidence or information known to the Government when the action was brought.

(B) For purposes of this paragraph, "senior executive branch official" means any officer or employee listed in paragraphs (1) through (8) of section 101(f) of the Ethics in Government Act of 1978 (5 U.S.C. App.).

(3) In no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party.

(4)(A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government [3] Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

(B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

(f) Government not liable for certain expenses.--The Government is not liable for expenses which a person incurs in bringing an action under this section.

(g) Fees and expenses to prevailing defendant.--In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

(h) Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief shall include reinstatement with the same seniority status such employee would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An employee may bring an action in the appropriate district court of the United States for the relief provided in this subsection.

CREDIT(S)

(Pub.L. 97-258, Sept. 13, 1982, 96 Stat. 978; Pub.L. 99-562, §§ 3, 4, Oct. 27, 1986, 100 Stat. 3154, 3157; Pub.L. 100-700, § 9, Nov. 19, 1988, 102 Stat. 4638; Pub.L. 101-280, § 10(a), May 4, 1990, 104 Stat. 162; Pub.L. 103-272, § 4(f)(1)(P), July 5, 1994, 108 Stat. 1362.)

Footnotes

1 See, now, Rule 4(i) of the Federal Rules of Civil Procedure.

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31 U.S.C.A. § 3730, 31 USCA § 3730
Current through P.L. 118-19. Some statute sections may be more current, see credits for details.

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81 FR 76307-01, 2016 WL 6459771(F.R.)
RULES and REGULATIONS
DEPARTMENT OF DEFENSE
Office of the Secretary
32 CFR Part 199
[Docket ID: DOD-2015-HA-0062]
RIN 0720-AB64

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE: Refills of Maintenance Medications Through Military Treatment Facility Pharmacies or National Mail Order Pharmacy Program

Wednesday, November 2, 2016

AGENCY: Office of the Secretary, Department of Defense (DoD).

***76307** ACTION: Final rule.

SUMMARY: This final rule implements section 702 (c) of the Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 which states that beginning October 1, 2015, the pharmacy benefits program shall require eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program. An interim final rule is in effect. Section 702(c) of the National Defense Authorization Act for Fiscal Year 2015 also terminates the TRICARE For Life Pilot Program on September 30, 2015. The TRICARE For Life Pilot Program described in section 716(f) of the National Defense Authorization Act for Fiscal Year 2013, was a pilot program which began in March 2014 requiring TRICARE For Life beneficiaries to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program. TRICARE for Life beneficiaries are those enrolled in the Medicare wraparound coverage option of the TRICARE program. This rule includes procedures to assist beneficiaries in transferring covered prescriptions to the mail order pharmacy program.

***76308** DATES: Effective Date: This rule is effective January 6, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. George Jones, Jr., Chief, Pharmacy Operations Division, Defense Health Agency, telephone 703-681-2890.

SUPPLEMENTARY INFORMATION:

A. Executive Summary

1. Purpose

This final rule implements Section 702(c) of the Carl Levin and Howard P. "Buck" McKeon National Defense Authorization Act for Fiscal Year 2015 which states that beginning October 1, 2015, the pharmacy benefits program shall require eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program. Eligible covered beneficiaries are defined in sections 1072(5) and 1086 of title 10, United States Code.

2. Summary of the Major Provisions of the Final Rule

TRICARE beneficiaries are generally required to obtain all prescription refills for select non-generic maintenance medications from the TRICARE mail order program (where beneficiary copayments are much lower than in retail pharmacies) or military treatment facilities (where there are no copayments). Covered maintenance medications are those prescribed for chronic, long-

term conditions that are taken on a regular, recurring basis, but do not include medications to treat acute conditions. TRICARE will follow best commercial practices, including that beneficiaries will be notified of the new rules and mechanisms to allow them to receive adequate medication during their transition to mail for their refills. The statute and rule authorize a waiver of the mail order requirement based on patient needs and other appropriate circumstances.

3. Costs and Benefits

The effect of the statutory requirement, implemented by this rule, is to shift a volume of prescriptions from retail pharmacies to the mail order pharmacy program. This will produce savings to the Department of approximately $81 million per year and savings to beneficiaries of approximately $20 million per year in reduced copayments.

B. Background

In Fiscal Year 2014, 61 million prescriptions were filled for TRICARE beneficiaries through the TRICARE retail pharmacy benefit at a net cost of $5.1 billion to the government. On average, the government pays 32% less for brand name maintenance medication prescriptions filled in the mail order program or military treatment facility pharmacies than through the retail program. Not all prescriptions filled through the retail program are maintenance/chronic medications. However, there is potential for significant savings to the government by shifting a portion of TRICARE prescription refills to the mail order program or military treatment facility pharmacies. In addition, there will be significant savings to TRICARE beneficiaries who will receive up to a 90 day refill at no charge for generics in the mail order program compared to $10 copay for up to a 30 day in retail. The savings is even greater for brand-name prescriptions: $20 for up to 90 days in mail versus $24 for up to 30 days in retail, meaning that for a 90-day supply the copayment comparison is $20 in mail to $72 in retail. The non-formulary copayment amount is $49 for up to 90 days in mail non-formulary drugs are generally not available in retail.

C. Summary of the Final Rule

The final rule revises paragraph (r) to 32 CFR 199.21. This paragraph (r) establishes rules for the new program of refills of maintenance medications for TRICARE through the mail order pharmacy program. Paragraph (r)(1) requires that for covered non-generic maintenance medications, TRICARE beneficiaries are generally required to obtain their prescription refills through the national mail order pharmacy program or through military treatment facility pharmacies. TRICARE beneficiaries are defined in sections 1072(5) and 1086 of title 10, United States Code, including those enrolled in the Medicare wraparound coverage option of the TRICARE program.

Paragraph (r)(2) provides that the Director, Defense Health Agency will establish, maintain, and periodically revise and update a list of covered maintenance medications, which will be accessible through the TRICARE Pharmacy Program Web site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis. It will be clinically appropriate and cost effective to dispense the medication from the mail order pharmacy. It will be available for an initial filling of a 30-day or less supply through retail pharmacies, and will be generally available at military treatment facility pharmacies for initial fill and refills. It will be available for refill through the national mail-order pharmacy.

Paragraph (r)(3) provides that a refill is a subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription, or a new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

Paragraph (r)(4) provides that a waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in several circumstances. There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance, for example, for nursing home residents. This waiver is obtained through

an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, Defense Health Agency.

Paragraph (r)(5) establishes procedures for the effective operation of the program. The Department will implement the program by utilizing best commercial practices to the extent practicable. An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented. Beneficiaries with active prescriptions for a medication on the maintenance medication list will be notified that their medication is covered under the program. Beneficiaries will be advised that they may receive up to two 30 day fills at retail while they transition their prescription to the mail order program. The beneficiary will be contacted after each of these two fills reminding the beneficiary that the prescription must be transferred to mail. Requests for a third fill at retail will be blocked and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance. The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program. In any case in which a beneficiary is required to obtain a maintenance medication prescription refill from the national mail-order pharmacy program and attempts instead ***76309** to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver or in taking any other appropriate action to meet the beneficiary's needs and to implement the program. The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

Paragraph (r)(6) provides that the program will remain in effect indefinitely with any adjustments or modifications required by law.

D. Summary of and Response to Public Comments

The interim final rule was published in the Federal Register (80 FR 46796) August 6, 2015, for a 60-day comment period. We received six comments on the interim final rule; four comments from individuals and two comments from professional associations. We appreciate these comments, which are summarized here, along with DoD's response.

Comment: One comment expressed concern regarding the possibilities of delays in the mail causing the patient to miss a day or more of their medication.

Response: The provisions of the TRICARE pharmacy contract permit beneficiaries to refill medications well in advance of the refill due date to allow for adequate shipping time. Additionally, this final rule provides for a case-by-case waiver to permit prescription maintenance medication refill at a retail pharmacy when necessary due to personal need or hardship, emergency, or special circumstance.

Comment: One commenter objected to the lack of clear communication from ESI by stating that conflicting messages are often given to a beneficiary who calls with a question, i.e. your medications has been shipped, your medication has not been shipped, etc. The same individual suggests that Prior Approvals for brand name products often get deleted from the system requiring the beneficiary to repeat the PA process.

Response: DoD acknowledges the commenter's concerns regarding contractor communication and Prior Approvals being deleted from the system, both of which are contract specific issues, and not part of the regulatory language. It should be noted that Prior Approvals may be time limited depending on the medication. DoD will consider the feedback for incorporation into future contractor customer service performance requirements.

Comment: One commenter inquired why Active Duty personnel are not required to participate in this mandatory program which appears to be targeting retirees. In addition, the individual suggested a blanket waiver be administered for retirees who live in remote areas with very limited MTF pharmacy access. A final concern asked if MTF staffing has been increased to accommodate the potential influx of retirees.

Response: This final rule conforms with the current statutory requirement of Section 702 in the fiscal year (FY) 2015 National Defense Authorization Act, requiring eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail order program. Eligible covered beneficiaries are defined in Title 10, Section 1072(5) and does not include Active Duty service members. The statute and the rule designate military treatment facility (MTF) pharmacies or the mail order pharmacy program as the two options available to beneficiaries for obtaining refills of non-generic prescription maintenance medications. For those beneficiaries who live in remote areas with limited MTF access, the mail order pharmacy program is an ideal option saving both time and copayment expenses. Our experience and data from the TRICARE FOR LIFE maintenance medication pilot showed that there was sufficient capacity to accommodate the change, both at mail order and in the MTFs. Our data show that the overall impact on the MTF workload was very minimal, while majority of the prescriptions went to mail order. The movement of brand maintenance medications from retail to mail order actually saves beneficiaries out-of-pocket expenses in the form of reduced copays and up to a 90 day supply for less than the 30 day copay at retail. This provides a win-win scenario for the beneficiary and the government.

Comment: One commenter cited anecdotal evidence in Alabama that resulted in emergency room visits from ingesting mail order prescriptions that had been exposed to excessive heat. The commenter expressed concerns about proper temperature control of medications shipped through the mail and suggests the rule include a requirement that all medications must be kept within the FDA's recommended range of 59-86 degrees.

Response: The pharmacy contractor reviews all medications dispensed through the mail order pharmacy for unique shipping requirements, based on information from the manufacturer. For medications that are temperature-sensitive, special shipping procedures are followed. The temperature-sensitive medications are mailed via expedited overnight shipping or 2nd day air, at no cost to the beneficiary. Before certain medications are delivered, a scheduling call is made to the beneficiary to arrange a delivery time and date.

Comment: A professional association commented with a number of concerns: beneficiaries should continue to have choice, flexibility, and easy access to prescription medications; unnecessary waste resulting from auto-ship policies and the suggestion to implement policies to ensure mail order refills are approved and needed; DoD should conduct and publicize a beneficiary satisfaction survey at the end of each year; beneficiaries should be properly informed about the options to seek a waiver and clear instructions on how to obtain one; DoD should develop and make available a complete list of acute care meds.

Response: This final rule conforms with the current statutory requirement of Section 702 in the FY 2015 NDAA requiring eligible covered beneficiaries generally to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail order program. DoD believes it is being implemented successfully and without adverse effects on beneficiaries. Non-generic prescription maintenance medications subject to the program are listed at www.health.mil/selectdruglist. DoD has determined it unnecessary to have an additional list to specify acute care medications that are not subject to the program. DoD continues to monitor beneficiary satisfaction of the TRICARE pharmacy program.

Comment: A professional association commented with the following concerns: The rule should clearly indicate that covered maintenance medications include non-generic only; beneficiaries should have to consent to getting a refill rather than automatic shipping; mandatory mail results in a silo approach where the patient gets prescriptions from multiple sources resulting the lack of coordinated care; community pharmacists are often the sole source for medication and patient education and can only judge the patient's understand by in-person interactions; communications to beneficiaries regarding waivers should include complete information on how to obtain a waiver.

Response: Section 199.21(r)(1) has been amended to insert “non-generic” ***76310** prior to “covered medications”. Contractor requirements are not part of the regulatory language. In order to participate in the mail order auto-ship program, beneficiaries must consent to auto-ship enrollment but are not required to do so. Beneficiaries enrolled in the auto-ship program are notified prior to medication shipment.

E. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review"

Executive Order (E.O.) 12866 requires that a comprehensive regulatory impact analysis be performed on any economically significant regulatory action, defined primarily as one that would result in an effect of $100 million or more in any one year. The DoD has examined the economic and policy implications of this final rule and based on the resulting analysis, the Office of Management and Budget has concluded that this is an economically significant regulatory action under the Executive Order. The program rule will produce savings to the Department of approximately $81M per year and savings to beneficiaries of approximately $20 million per year in reduced copayments. This rule results in a shift of workload from retail pharmacies to the mail order program. This workload shift is estimated to result in a net impact to retail pharmacy margins nationwide of $15.6 million in FY17 dollars. This rule has been designated an economically significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB).

Congressional Review Act, 5 U.S.C. 801, et seq.

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This final rule is not a major rule under the Congressional Review Act.

Section 202, Public Law 104-4, "Unfunded Mandates Reform Act"

This rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

The Regulatory Flexibility Act (RFA) requires that each Federal agency prepare and make available for public comment, a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This final rule does not have a significant impact on a substantial number of small entities.

Public Law 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

This final rule contains no new information collection requirements subject to the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3511).

Executive Order 13132, "Federalism"

This final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on the States; the relationship between the National Government and the States; or the distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Administrative practice and procedure, Claims, Dental health, Fraud, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—[AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.
32 CFR § 199.21
2. Section 199.21 is amended by revising paragraph (r) to read as follows:
32 CFR § 199.21

§ 199.21 TRICARE Pharmacy Benefits Program.
* * * * *
(r) Refills of maintenance medications for eligible covered beneficiaries through the mail order pharmacy program—(1) In general Consistent with section 702 of the National Defense Authorization Act for Fiscal Year 2015, this paragraph requires that for non-generic covered maintenance medications, beneficiaries are generally required to obtain their prescription through the national mail-order pharmacy program or through military treatment facility pharmacies. For purposes of this paragraph, eligible covered beneficiaries are those defined under sections 1072 and 1086 of title 10, United States Code.

(2) Medications covered. The Director, DHA, will establish, maintain, and periodically revise and update a list of non-generic covered maintenance medications subject to the requirement of paragraph (r)(1) of this section. The current list will be accessible through the TRICARE Pharmacy Program Internet Web site and by telephone through the TRICARE Pharmacy Program Service Center. Each medication included on the list will meet the following requirements:

(i) It will be a medication prescribed for a chronic, long-term condition that is taken on a regular, recurring basis.

(ii) It will be clinically appropriate to dispense the medication from the mail order pharmacy.

(iii) It will be cost effective to dispense the medication from the mail order pharmacy.

(iv) It will be available for an initial filling of a 30-day or less supply through retail pharmacies.

(v) It will be generally available at military treatment facility pharmacies for initial fill and refills.

(vi) It will be available for refill through the national mail-order pharmacy program.

(3) Refills covered. For purposes of the program under paragraph (r)(1) of this section, a refill is:

(i) A subsequent filling of an original prescription under the same prescription number or other authorization as the original prescription; or

(ii) A new original prescription issued at or near the end date of an earlier prescription for the same medication for the same patient.

(4) Waiver of requirement. A waiver of the general requirement to obtain maintenance medication prescription refills from the mail order pharmacy or military treatment facility pharmacy will be granted in the following circumstances:

(i) There is a blanket waiver for prescription medications that are for acute care needs.

(ii) There is a blanket waiver for prescriptions covered by other health insurance.

(iii) There is a case-by-case waiver to permit prescription maintenance medication refills at a retail pharmacy when necessary due to personal need or hardship, emergency, or other special circumstance. This waiver is obtained through an administrative override request to the TRICARE pharmacy benefits manager under procedures established by the Director, DHA.

(5) Procedures. Under the program established by paragraph (r)(1) of this section, the Director, DHA will establish ***76311** procedures for the effective operation of the program. Among these procedures are the following:

(i) The Department will implement the program by utilizing best commercial practices to the extent practicable.

(ii) An effective communication plan that includes efforts to educate beneficiaries in order to optimize participation and satisfaction will be implemented.

(iii) Beneficiaries with active retail prescriptions for a medication on the maintenance medication list will be notified that their medication is included under the program. Beneficiaries will be advised that they may receive two 30 day fill at retail while they transition their prescription to the mail order program.

(iv) Requests for a third fill at retail will result in 100% patient cost shares and will be blocked from any TRICARE payments and the beneficiary advised to call the pharmacy benefits manager (PBM) for assistance.

(v) The PBM will provide a toll free number to assist beneficiaries in transferring their prescriptions from retail to the mail order program. With the beneficiary's permission, the PBM will contact the physician or other health care provider who prescribed the medication to assist in transferring the prescription to the mail order program.

(vi) In any case in which a beneficiary required under paragraph (r) of this section to obtain a maintenance medication prescription refill from national mail order pharmacy program and attempts instead to refill such medications at a retail pharmacy, the PBM will also maintain the toll free number to assist the beneficiary. This assistance may include information on how to request a waiver, consistent with paragraph (r)(4)(iii) of this section, or in taking any other appropriate action to meet the beneficiary's needs and to implement the program.

(vii) The PBM will ensure that a pharmacist is available at all times through the toll-free telephone number to answer beneficiary questions or provide other appropriate assistance.

(6) This program will remain in effect indefinitely with any adjustments or modifications required by law.

* * * * *

Dated: October 28, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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